DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	7/11/2024-7/19/2024*
	FEI NUMBER 3004149463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Dr. Kiran S. Divi, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Divi's Laboratories Ltd. (Unit II)	Chippada Village, Annavaram, Bheemunipatnam Mandal
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Visakhapatnam District, Andhra Pradesh, 531162 India	API Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 1

Written procedures are not established for the cleaning of equipment used in the manufacture API.

Specifically, SOP [redacted (b) (4)] CLEANING PROCEDURES", SOP NO: PD/OP/0017, REV NO: 000, EFFECTIVE DATE: 01/01/2021, does not include provisions to clean or visually inspect the area behind the [redacted (b) (4)] of [redacted (b) (4)] are used in the manufacture of [redacted (b) (4)] [redacted (b) (4)]

*DATES OF INSPECTION

7/11/2024(Thu), 7/12/2024(Fri), 7/15/2024(Mon), 7/16/2024(Tue), 7/17/2024(Wed), 7/18/2024(Thu), 7/19/2024(Fri)

X Andrew Le
Investigator
Signed By: 2002899628
Date Signed: 07-19-2024 11:39:58

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Khoa Nathan V Tran, Investigator Andrew Le, Investigator	X Khoa Nathan V Tran Investigator Signed By: 2003026741 Date Signed: 07-19-2024 11:39:36	7/19/2024